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09/881,213	06/15/2001	Bengt E.B. Sandberg	33700WC004	5134

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/881,213

Applicant(s)

Sandberg et al

Examiner

R.S. Travers J.D., Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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The amendment filed June 30, 2003 has been received and entered into the file.

Applicant's arguments filed June 30, 2003 have been fully considered but they are not deemed to be persuasive.

The election filed November 8, 2002 has been received and entered into the file.

Claims 1-20 are presented for examination.

Applicant's election without traverse of Group I claims 1-11 in Paper No. 7 is acknowledged.

Claims 12-20 reading on non-elected subject matter are withdrawn from consideration

This application contains claims 12-20 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Examiner suggests the term "reagent" be substituted for the term "it" in claim 11 to avoid confusion with regard to the nature of the entity envisioned.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-11, and 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Norrgren et al and Chen et al in view of Wilbur et al.

Norrgren et al and Chen et al teach the use of extracorporeal methods for providing and enhancing various therapeutic regimens, to include radio nuclide anti-cancer therapy. Norrgren et al and Chen et al teach the useful nature of extracorporeal extraction of various toxic medicaments, bound and unbound, employing various specific adsorption columns (see Norrgren et al figure 1). Chen et al teach the desirability of extracorporeal extraction via immunoabsorption for various therapeutic regimens (see figure 3). Wilbur et al teach the claimed trifunctional linkers as old and well known in combination with various specific therapeutic functional moieties, as herein claimed (see page 20, paragraph 2). These medicaments are taught as useful for adsorbing to a column for extracting various compounds (see page 2, lines 1-2). Claims 1-11, 21-24 and the primary references, differ as to:

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1) the specific recitation of the prior art trifunctional linkers for loading extracorporeal columns, and

2) those specific linker lengths herein claimed.

As stated above, Wilber et al teach the instant trifunctional linking compounds as useful for adsorbing to a column for extracting various compounds (see page 2, lines 1-2). Norrgren et al teach the useful nature of extracorporeal extraction of various toxic medicaments, bound and unbound, employing various specific adsorption columns (see Norrgren et al figure 1). In figure 1, Norrgren et al illustrate the use of a column with specific adsorbed linkers for removing toxic medicaments extracorporeally, as herein claimed. This teaching would have motivated the skilled artisan to employ various linking agents, such as those taught by Wilber et al, in removing toxic agents extracorporeally. Attention is directed to Wilber et al teaching problems of stearic hindrance with employing various linking compounds; with these hindrance problems overcome with those linkers disclosed by Wilber et al (see pages 38-40) motivating the skilled artisan to employ those linkers taught by Wilber et al. Stearic hindrance is taught by Wilber et al as reduced by his linking agents (see compounds 46 and 48), and with the ideal linker chain length being 20-60 angstroms (see page 29). Possessing the Examiner cited prior art, the skilled artisan would have been motivated to employ extracorporeal extraction of toxins associated with therapeutic regimens. Wilber et al teach the instant trifunctional linking agents as old and well

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known for linking the claimed various specific therapeutic functional moieties, as herein claimed (see page 20, paragraph 2). It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-inflammatory agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). The skilled artisan possessing the Examiner cited teachings would have seen trifunctional linking compositions, and the administration of these compounds to columns for extracorporeal extraction of therapeutic toxins as residing in the skilled artisan purview.

### **RESPONSE TO ARGUMENTS**

New claims 12-15 have been renumbered as claims 21-24 under 37 CFR 1.126 due to the previous submission of claims numbered 12-20.

Attention is directed to Wilber et al teaching trifunctional compounds to effect "extracorporeal immunoabsorptive removal methods" indistinguishable from those herein claimed. Simple perusal of the Wilbur et al publication supplies the skilled

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artisan with those ingredients to practice the invention as claimed. Failure of Wilbur et al to specifically disclose those compounds herein claimed, precludes anticipation by Wilbur et al, but has little effect on this patent's powers of obviation. Those specific linking agents envisioned by Applicants are disclosed at page 11 (see Wilbur et al page 1, examples 1-8, especially no. 1). At page 14, Wilbur et al teach those core moieties herein envisioned as useful for the extracorporeal use claimed herein (see page 14, example 30). Although Wilbur et al fails to recite the linker arm length herein disclosed, guidance is provided to reach those compounds envisioned by Applicants. At page 15, Wilbur et al teach a minimum arm length of 9 angstroms, with a preferred length of 6-20 atoms encompassing those arm lengths set forth in the instant claims. Additionally, Wilbur et al teach ether linkages, as employed by Applicants, as beneficial to "aid in the water solubilization of the Biotin moiety" (see page 15, paragraph 2).

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither clear, convincing, nor reasonably commensurate in scope with the instant claims. Absent claims commensurate with the showing of unexpected benefits, or a showing

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reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as constructively averred herein.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

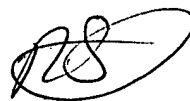
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE



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MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to be 'RTS' or similar, enclosed within a circular flourish.

**Russell Travers J.D., Ph.D.**  
**Primary Examiner**  
**Art Unit 1617**